REMARKS

Claims 1, 6-8 and 18 remain pending in the application. The pending claims have been rejected under 35 U.S.C. 101, 112, first paragraph, and 102(a). Applicants have reviewed the grounds for the rejections, but traverse for the reasons set forth below.

I. Rejection Under 35 U.S.C. 101

Claims 1, 6-8 and 18 stand rejected as lacking a credible, specific and substantial utility or a well established utility. Applicants continue to maintain the specification provides several credible, specific and substantial uses for flea HMT nucleic acid molecules and proteins encoded by such nucleic acid molecules.

One such utility is the use of the claimed nucleic acid molecules as genetic vaccines. See, e.g., pages 70, line 21, through page 73, line 13. For example, on page 72, lines 21-14, the specification notes that "a recombinant virus vaccine comprising a flea HMT and/or HNC nucleic acid molecule of the present invention is administered according to a protocol that results in the animal *producing a sufficient immune response* to protect itself from flea infestation" (emphasis added). This utility is credible when read in conjunction with the teachings of U.S. Patent No. 5,766,602 ('602 Patent), which is incorporated by reference in its entirety on page 72 of the specification. The '602 Patent clearly provides sufficient evidence throughout the specification that such genetic recombinant vaccines have credible utility. See, in particular, Examples 5 and 6 of the '602 Patent.

Applicants, accordingly, contend at least one credible, specific and substantial use of the flea HMT nucleic acid molecules is provided in the specification and request the withdrawal of the rejection.

II. Rejection Under 35 U.S.C. 112 (Enablement)

Claims 1, 6-8 and 18 also stand rejected as failing to enable one skilled in the art to use the claimed invention based on the specification failing to provide a credible, substantial or specific utility as stated for the 35 U.S.C. 101 rejection. As argued above, Applicants submit the specification provides at least one credible, specific and substantial utility for the claimed nucleic acid molecules. Applicants further submit the specification provides sufficient teaching to enable one skilled in the art to use the claimed invention. It has long been well-recognized that the teachings within a specification are presumed to be accurate unless the Patent Office can provide objective evidence to the contrary. See, *In*

re Marzocchi, 169 USPQ 367, 369 (CCPA 1971). See, also, *Fiers v. Revel v. Sugano*, 25 USPA2d 1601, 1607 (Fed. Cir. 1993), in which the Federal Circuit (in quoting *In re* Marzocchi) stated:

> [A] specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented *must* be taken in as in compliance with the enabling requirement of the first paragraph of Section 112 *unless* there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support...[A]ny party making the assertion that a U.S. patent specification or claims fails, for one reason or another, to comply with Section 112 bears the burden of persuasion in showing said lack of compliance."

The CCPA, the predecessor court to the Federal Circuit, has also recognized "that the PTO has the burden of giving reasons, supported by the record as a whole, why the specification is not enabling...Showing that the disclosure entails undue experimentation is part of the PTO's initial burden...." See, *In re Angstadt*, 190 USPQ 214, 219 (CCPA 1976).

Here, Applicants have disclosed several uses and have given detailed guidance to those skilled in the art for carrying out such uses throughout the specification, including the use described on pages 71-73 discussed above. Applicants further submit the initial burden of showing the specification is not enabling or entails undue experimentation has not been met by the PTO. Based on the guidance provided by the Federal Circuit and its predecessor court, it is clear that mere conclusory statements of non-enablement is not sufficient to overcome this initial burden. Applicants, likewise, request the withdrawal of this rejection.

III. Rejection under 35 U.S.C. 112 (written description)

Since Claim 1 now only relates to SEQ.ID.NO:26, Applicants submit this rejection is now moot.

IV. Rejection under 35 U.S.C. 112, second paragraph

Claim 1, and by dependence, the remaining claims, stand rejected as being vague and indefinite in the recitation of "capable of." Although Applicants believe the recitation of this phrase is sufficiently definite and has been used in many claims of issued patents, Applicants have nevertheless amended Claim 1 to expedite the prosecution of this application.

V. Rejection under 35 U.S.C. 102(b)

Applicants contend this rejection is now moot in light of the amendment to Claim 1.

CONCLUSION

In light of the foregoing amendments and remarks, Applicants request the withdrawal of the rejections and solicit an allowance of the claims. The Examiner is invited to contact the undersigned should any issues remain.

Respectfully submitted,

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